Remarks

Claims 1, and 3-22 remain pending in the application after entry of this amendment. Claim 2 has been cancelled herein. Claims 1, 12, 19, and 21 have been amended as shown above. The claims were amended to more fully clarify the invention. No new matter has been added by the amendments above, specifically, the amendments to claims 1, 19, and 21 were undertaken to incorporate the subject matter of claim 2 into those claims, and claim 12 was made independent. Favorable reconsideration is respectfully requested in light of the above amendments and the following comments.

The Examiner has rejected claims 1-16 and 18-22 under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 6,432,039 (Wardle). Applicants respectfully traverse this rejection.

The Examiner has rejected claim 17 under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 4,827,932 (Ideker). Applicants respectfully traverse this rejection.

The Examiner has rejected claims 1 and 3 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,147,279 (Girard). Applicants respectfully traverse this rejection.

35 U.S.C. Rejection over Wardle '039

The Examiner has rejected claims 1-16 and 18-22 under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 6,432,039 (Wardle). The Examiner asserts that Wardle teaches a device for treating cardiac disease, the device having a jacket of flexible material that is adapted to be secured to the heart and adapted to be adjusted on the heart to snugly conform to an external geometry of the heart and assume a maximum adjusted volume; and a delivery source for delivery of one or more therapeutic agents to the surface of the heart.

Applicants respectfully assert that newly amended claim 1 is not anticipated by the device of Wardle '039. Claim 1 has been amended to recite that the jacket is an elastic material. Applicants assert that Wardle '039 does not disclose this limitation. Beginning at line 66 of column 3, Wardle '039 discusses details about the jacket. Wardle '039 states that the cardiac reinforcement device comprises a frame or containment structure formed of a high strength biocompatible mesh-like material (col. 3, line 67- col.

Received from < 6123329081 > at 2/24/03 5:27:17 PM [Eastern Standard Time]

4, line 6). The high strength mesh is said to serve three purposes, including providing a strong, flexible, **non-elastic** support for the containment structure (emphasis added, col. 4, lines 6-9). Wardle continues to discuss the biocompatible materials that can be used in the device stating that other suitable biocompatible materials may be selected, as long as the resultant structure is compliant, **but not elastic** (emphasis added, col. 4, lines 14-16). Because it is specifically stated that the device of Wardle '039 is non-elastic, Applicants respectfully assert that Wardle '039 does not anticipate the pending claims. Applicants therefore request that this rejection be withdrawn.

Although not raised by the Examiner, Applicants respectfully assert that Wardle does not render the claimed invention obvious. Wardle '039 specifically states that the device should be non-elastic, therefore, one of skill in the art would not have been motivated to modify the device contrary to the teaching of Wardle '039 and make the device elastic.

Amended claim 12, which does not require that the jacket be made of elastic material is not anticipated because Wardle '039 does not disclose that the delivery source can be a coating. Wardle '039 only discloses that the delivery source be a drug delivery line 389, a portion of which wraps around the exterior surface of the device (col. 8, lines 36-41). Therefore, claim 12 is not anticipated by Wardle, and Applicants respectfully request that this rejection be withdrawn.

35 U.S.C. § 102 Rejection over Ideker '932

The Examiner has rejected claim 17 under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 4,827,932 (Ideker). The Examiner asserts that Ideker '932 teaches a device for treating cardiac disease of a heart having a jacket of flexible material, which is adapted to be secured to the heart and adapted to be adjusted on the heart to snugly conform to an external geometry of the heart; and a delivery source for delivery of one or more therapeutic agents to the surface of the heart, where the delivery device is a separable element 55 in the form of a bioadhesive.

Applicants respectfully assert that Ideker '932 does not anticipate the claimed invention. The bioadhesive utilized in Ideker '932 appears to be used to secure the device to the heart (col. 6, lines 10-16). There is no mention in Ideker '932 of the bioadhesive,

Received from < 6123329081 > at 2/24/03 5:27:17 PM [Eastern Standard Time]

or any other structure that is or would be capable of being a delivery source. Furthermore, the patch electrodes of Ideker '932 are not elastic as is required by amended claim 1, on which claim 17 is dependent.

Because at the least, Ideker '932 does not disclose a delivery source for the delivery of therapeutic agents, or any structure that is capable of functioning as a delivery source, Applicants respectfully request that this rejection be withdrawn. Applicants also respectfully assert that in Ideker '932 would not suggest to one of skill in the art that the device could be made elastic or be utilized or modified to contain a delivery source for therapeutic agents.

Obviousness type double patenting over Girard '279

The Examiner has rejected claims 1 and 3 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,147,279 (Girard). Applicants respectfully disagree with the Examiner. Applicants assert that claim 1 of Girard '279 is patentably distinct from pending claims 1 and 3.

Claim 1 of Girard '279 recites: A device for treating cardiac disease of a heart having a longitudinal axis from an apex to a base and having an upper portion and a lower portion divided by an A-V groove, the device comprising:

a jacket of flexible material of open cell construction defining a volume between an open upper end and a lower end, said jacket dimensioned for said apex of said heart to be inserted into said volume through said open upper end and for said jacket to be slipped over said heart, said jacket further dimensioned for said jacket to have a longitudinal dimension between said upper and lower ends sufficient for said jacket to constrain said lower portion;

said jacket adapted to be adjusted on said heart to snugly conform to an external geometry of said heart and assume a maximum adjusted volume for said jacket to constrain circumferential expansion of said heart beyond said maximum adjusted volume during diastole and permit substantially unimpeded contraction of said heart during systole;

an indicator for indicating when said jacket is adjusted on said heart to a desired degree of tensioning.

Received from < 6123329081 > at 2/24/03 5:27:17 PM [Eastern Standard Time]

Applicants respectfully assert that there is no disclosure or suggestion of a delivery source in claim 1 of Girard '279. The Examiner states that pending claims 1 and 3 are a broader version of claim 1 of Girard '279. Applicants respectfully disagree with this characterization. Claim 1 of Girard '279 requires an indicator for indicating when said jacket is adjusted on said heart to a desired degree of tensioning. Conversely, pending claims 1 and 3 recite, amongst other things, a delivery source for the delivery of one or more therapeutic agents to the surface of the heart. An indicator, and a delivery source are entirely separate and unrelated structures, and the recitation of one would in no way suggest the other. Applicants respectfully request that this rejection be withdrawn in light of the above comments.

Conclusion

In view of the amendments and comments presented herein, favorable reconsideration in the form of a Notice of Allowance is respectfully requested.

Respectfully submitted,

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Received from < 6123329081 > at 2/24/03 5:27:17 PM [Eastern Standard Time]

Marked up version of Claims

In the Claims

Please cancel claim 2 without prejudice. Please amend claims 1, 12, 19, and 21 as follows.

1. (Amended) A device for treating cardiac disease of a heart having an upper portion and a lower portion divided by an A-V groove, the device comprising:

a. a jacket of flexible, elastic material defining a volume between an upper end and a lower end, the jacket adapted to be secured to the heart and adapted to be adjusted on the heart to snugly conform to an external geometry of the heart and assume a maximum adjusted volume for the jacket to constrain circumferential expansion of the heart beyond the maximum adjusted volume during diastole and permit substantially unimpeded contraction of the heart during systole; and

b. a delivery source for the delivery of one or more therapeutic agents to the surface of the heart.

12. (Amended) A device for treating cardiac disease of a heart having an upper portion and a lower portion divided by an A-V groove, the device comprising:

a. a jacket of flexible material defining a volume between an upper end and a lower end, the jacket adapted to be secured to the heart and adapted to be adjusted on the heart to snugly conform to an external geometry of the heart and assume a maximum adjusted volume for the jacket to constrain circumferential expansion of the heart beyond the maximum adjusted volume during diastole and permit substantially unimpeded contraction of the heart during systole; and

b. a [The device according to claim 1 wherein the] delivery source compris[es]ing a coating on the jacket for the delivery of one or more therapeutic agents to the surface of the heart.

19. (Amended) A method for treating cardiac disease of a heart having an upper portion and a lower portion divided by an A-V groove, the method comprising:

Received from < 6123329081 > at 2/24/03 5:27:17 PM [Eastern Standard Time]

c. surgically accessing the heart;

d. applying a treatment device on the heart, the device comprising:

3) a jacket of flexible, elastic material defining a volume between an upper end and a lower end, the jacket adapted to be secured to the heart and adapted to be adjusted on the heart to snugly conform to an external geometry of the heart and assume a maximum adjusted volume for the jacket to constrain circumferential expansion of the heart beyond the maximum adjusted volume during diastole and permit substantially unimpeded contraction of the heart during systole; and

4) a delivery source for the delivery of one or more therapeutic agents to the surface of the heart;

e. securing the treatment device to the heart; and

f. surgically closing access to the heart while leaving the treatment device on the heart.

21. (Amended) A method for providing controlled and sustained administration of one or more therapeutic agents effective in treating cardiac disease, the method comprising surgically implanting a sustained therapeutic agent delivery system at a desired location on the heart, the therapeutic agent delivery system comprising:

a. a jacket of flexible, elastic material defining a volume between an upper end and a lower end, the jacket adapted to be secured to the heart and adapted to be adjusted on the heart to snugly conform to an external geometry of the heart and assume a maximum adjusted volume for the jacket to constrain circumferential expansion of the heart beyond the maximum adjusted volume during diastole and permit substantially unimpeded contraction of the heart during systole; and

c. a delivery source for the delivery of one or more therapeutic agents to the surface of the heart.

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Received from < 6123329081 > at 2/24/03 5:27:17 PM [Eastern Standard Time]